

## **Just Say No to Legal Immunity for Drug Manufacturers**

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North Carolina legislators are considering a bill that would bar lawsuits by consumers against pharmaceutical manufacturers that market dangerous and defective drugs. The drug immunity bill would directly harm North Carolina residents, while providing no benefit to our state's economy. Before it enacts a law to shield drug companies from accountability, the legislature should consider the painful lessons learned in Michigan and the limitations of FDA regulation.

### To Boost Profits for Multinational Drug Companies, Michigan Forfeits its Citizens' Rights

In 1996, Michigan legislators stripped state residents of their right to hold pharmaceutical companies responsible for injuries caused by dangerous drugs. Under Michigan law, so long as a drug has received the approval of the Food and Drug Administration (FDA), even if the drug turns out to be unsafe and causes physical injuries or death, Michigan residents cannot bring a lawsuit for damages.<sup>1</sup>

By writing FDA preemption into state law, Michigan gives all pharmaceutical companies immunity from claims that they failed to adequately warn consumers about the risks involved in taking a drug. Sixteen years later, only Texas had joined Michigan in conferring immunity on drug manufacturers.<sup>2</sup>

So, what did Michigan and its citizens gain in return for legislators nullifying fundamental rights of access to the courts? *Absolutely nothing.* Lobbyists and legislators touted the bill as a vehicle for attracting drug companies and creating jobs, even though out-of-state multinational companies benefited from the immunity. Twelve years after this "pro-business" bill was enacted, Pfizer, one of the most profitable pharmaceutical companies in the world and a major local employer, began closing up shop in Michigan. By the end of 2008, Pfizer had moved most of its Michigan operations to other states and overseas, leaving behind 2,100 laid-off workers, a two

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<sup>1</sup> Mich. Comp. Laws § 600.2946(5).

<sup>2</sup> Texas enacted a similar drug immunity statute in 2003. Tex. Civ. Prac. & Rem Code § 82.007.

million square foot vacant property, and a shaken community that had relied on the company as its largest taxpayer. Local business leaders described Pfizer's departure as a "gut punch."<sup>3</sup>

So, what have Michigan and its citizens lost because of the immunity statute? Consider the Vioxx fiasco:

- More than 50,000 people in the United States suffered a fatal heart attack or stroke because they took Vioxx.<sup>4</sup> In Michigan – unlike every other state – the law barred wrongful death claims against Merck, the manufacturer of Vioxx.
- Unlike every other state government, Michigan was prohibited from pursuing a civil claim against Merck for deceptive advertising and marketing practices. Citing Michigan's "only one of its kind" immunity law, the Michigan Court of Appeals in 2011 held that the state was barred from recovering the \$20,000,000 it had paid for Vioxx prescribed to Medicaid beneficiaries. *Attorney General v. Merck Sharp & Dohme Corp.*, 292 Mich. App. 1 (March 17, 2011).

In short, the state of Michigan has forfeited its ability to hold pharmaceutical companies accountable for misconduct. The result? Bigger profits for multinational drug companies, uncompensated tragedies for Michigan residents, and a \$20 million loss for Michigan taxpayers.<sup>5</sup>

### FDA Regulation Is Insufficient to Protect Consumers from Dangerous Drugs

It is vitally important that North Carolina residents and our Attorney General retain access to the courts for claims against drug companies. The FDA alone cannot protect consumers from dangerous and defective drugs. Few lawmakers are aware of important facts about the FDA and the drug approval process:<sup>6 7</sup>

- The FDA does not test drugs.
- The FDA relies on data submitted by the drug companies for approval purposes.

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<sup>3</sup> <http://www.annarbor.com/business-review/5th-anniversary-of-pfizer-gut-punch-ann-arbor-leaders-recall-rallying-cry/>

<sup>4</sup> <http://www.nytimes.com/2005/03/02/politics/02fda.html> (FDA official in 2005 estimates 55,000 deaths caused by Vioxx).

<sup>5</sup> <http://farmingtonhills.injuryboard.com/fda-and-prescription-drugs/michigans-drug-industry-immunity-law-michigan-citizens-fight-for-your-rights.aspx?googleid=289488>

<sup>6</sup> <http://thenewamerican.com/usnews/health-care/4038-avandia-a-case-study-in-big-pharma-fda-collusion>

<sup>7</sup> <http://www.jabfm.com/content/14/5/362.full.pdf>

- Since enactment of the Prescription Drug User Fee Act (PDUFA) in 1992, the FDA's drug approval arm, the Center for Drug Evaluation and Research (CDER), receives about 50% of its budget directly from pharmaceutical companies.
- If a pharmaceutical company wants a drug "fast tracked" for approval, it pays the FDA an extra fee.
- FDA employee performance evaluations are tied to the quantity of drug application approvals.
- After a drug is on the market, the FDA largely relies on the pharmaceutical company to report "related" adverse events.
- By approving a drug for market, the FDA is not making a determination that the drug is the optimal therapy for a condition.

The advertising and lobbying practices of the pharmaceutical industry heighten the need for consumer protection:<sup>8 9</sup>

- The United States and New Zealand are the only two developed nations that permit direct-to-consumer advertising of prescription drugs.
- The pharmaceutical industry spends almost twice as much on advertising a drug as it does on research and development.
- The average number of prescriptions for new drugs with direct-to-consumer advertising is nine times greater than prescriptions for drugs without direct-to-consumer advertising.
- PhRMA, the trade group representing the pharmaceutical industry in the United States, spent \$26,150,520 on lobbying efforts in 2009.<sup>10</sup>
- PhRMA donated \$31.6 million to political candidates in 2010.<sup>11</sup>

Drug company lobbyists and their legislative allies in Michigan argued that consumers would be protected by a "fraud on the FDA exception" in the immunity statute.<sup>12</sup>

The "fraud exception" has two fundamental flaws. First, the drug lobbyists carefully drafted the immunity statute so that proving fraud is impossible. Henry Greenspan, a Michigan expert on the pharmaceutical industry, explained:

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<sup>8</sup> <http://www.sciencedaily.com/releases/2008/01/080105140107.htm>

<sup>9</sup> <http://www.csa.com/discoveryguides/direct/review2.php>

<sup>10</sup> Center for Responsive Politics, [PhRMA 2010 Lobbying](#), OpenSecrets.org lobbying database (accessed July 10, 2011).

<sup>11</sup> <http://www.opensecrets.org/news/2011/09/opensecrets-mailbag-lobbying-bribery-big-pharma.html>

<sup>12</sup> Mich. Comp. Laws § 600.2946(5)(a).

Those who propose preemption laws try to mask the attack on consumer protection by including a clause suggesting that companies can be sued if FDA finds that the manufacturer committed fraud in the approval process. What we are not told, however, is that FDA never makes such findings. That is because conviction of fraud against the FDA—a serious felony—would bar a company from participation in federal programs like Medicare, Medicaid, or the VA.

For that reason, when FDA has “the goods” on a company, the consequences are a plea bargain yielding monetary fines, admission of misdemeanors, and a “corporate integrity agreement” in which a company promises to do better (many companies carry several such agreements). None of this qualifies as fraud conviction. The so-called “fraud exception” is thus itself fraudulent.<sup>13</sup>

Second, the FDA’s drug approval process cannot be 100 percent effective in preventing dangerous drugs from coming to market or mandating their withdrawal before they cause injuries or deaths. As the Supreme Court observed “[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.”<sup>14</sup> On numerous occasions, after securing FDA approval, drug companies launched massive marketing campaigns, received and ignored multiple reports of adverse events, and continued to sell the drug without adequate warnings. While Vioxx is the most glaring example of the FDA’s failure to protect the public from a dangerous drug, other notorious examples include fen-phen, Baycol, Rezulin and Avandia. All of these popular drugs were withdrawn from the market – after they had injured or killed thousands of American consumers.

### North Carolina Should Reject Immunity for Pharmaceutical Companies

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court held that FDA approval of a medication or the warning label does not shield the drug manufacturer from liability under state law. Having failed to achieve nationwide FDA preemption in *Wyeth*, the pharmaceutical industry shifted its campaign for immunity to state legislatures. Its first target was North Carolina, where a new legislative majority was viewed as an easy target for pharmaceutical industry lobbyists.

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<sup>13</sup> [http://www.journaltimes.com/news/opinion/editorial/article\\_71b87a88-0428-11e1-a672-001cc4c03286.html](http://www.journaltimes.com/news/opinion/editorial/article_71b87a88-0428-11e1-a672-001cc4c03286.html)

<sup>14</sup> *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009).  
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North Carolina legislators outsourced the work of drafting a bill to the American Legislative Exchange Council (ALEC),<sup>15</sup> a conservative corporate advocacy group whose “Private Enterprise Board” includes GlaxoSmithKline Vice-President John Del Giorno, PhRMA Senior VP Jeffrey Bond, and Pfizer Director of Government Relations Robert Jones.<sup>16</sup> In March 2011, North Carolina House members introduced a sweeping products immunity bill<sup>17</sup> that was a verbatim replica of ALEC’s “model legislation.”<sup>18</sup>

The original bill provided immunity for manufacturers of *all* products sold in North Carolina, as long as the product had been approved by some federal or state agency. At the committee hearing on March 31, 2011, Janet Ward Black, former president of the North Carolina Advocates for Justice (NCAJ) and the North Carolina Bar Association, informed legislators and the public of the enormous scope of the proposed legislation. As an example, she noted that the bill would give complete immunity to out-of state manufacturers who sold contaminated baby food to North Carolina consumers, while consumers in every other state could pursue claims for their babies’ injuries.

Stung by criticism, the bill sponsors made a strategic retreat to protect the pharmaceutical industry, the driving force behind the legislation. They submitted an amended bill, making drug manufacturers the sole beneficiaries of the statutory immunity.<sup>19</sup> To ensure that the “fraud on the FDA” exception was toothless, the bill provided that the exception would apply only if the manufacturer “[i]ntentionally, and in violation of applicable regulations *as determined by final agency action*, withheld from or misrepresented to the United States Food and Drug Administration information material to the approval or maintaining of approval of the drug...”<sup>20</sup> Because the FDA *never* issues a determination of fraud, no plaintiff could ever invoke the exception.

NCAJ members alerted clients whose family members died because pharmaceutical companies continued to market drugs without adequate warnings despite knowledge that the drugs were unsafe. Grieving husbands and parents sent compelling letters to legislators and testified against the immunity bill. The victims were joined by North Carolina’s Attorney General, who

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<sup>15</sup> See <http://www.alec.org>; “The Big Money Behind State Laws,” Editorial Board, New York Times (February 12, 2012); Center for Media and Democracy, <http://www.alecexposed.org>.

<sup>16</sup> <http://www.alec.org/about-alec/private-enterprise-board/> (accessed February 13, 2012). John Del Giorno, GlaxoSmithKline VP and member of the ALEC Private Enterprise Board, was the first speaker invited to address the North Carolina House Tort Reform Committee when HB 542 was presented on March 23, 2011

<sup>17</sup> House Bill 542, March 31, 2011 (Section 3.1).

<sup>18</sup> American Legislative Exchange Council, “The State Factor” at 9-10 (“ALEC Model Regulatory Compliance with Liability Act” (“Option 1 – No Liability”)) (June 2009).

<sup>19</sup> House Bill 542, Committee Substitute Favorable 5/10/11 (Section 2.2).

<sup>20</sup> Id. (emphasis added).

informed the legislature that the bill would cost the State millions of dollars in potential claims against drug companies.<sup>21</sup> And NCAJ questioned the need for a bill that would directly harm North Carolina residents, create no North Carolina jobs, and benefit only multinational drug companies.

Brushing aside these objections, the sponsors quickly pushed the bill through the House Tort Reform Committee. On June 1, 2011, the House passed a comprehensive “tort reform” bill (HB 542), including the drug immunity provision.<sup>22</sup> The Attorney General responded: “We continue to be concerned that this law could be a loss for taxpayers and consumers. It’s difficult to understand why the legislature would make it harder for North Carolina to take action against drug companies that hurt patients or deceive the government, especially when other states don’t have these obstacles.”<sup>23</sup>

In the Senate, after several members expressed misgivings, the sponsors of HB 542 removed the drug provision.<sup>24</sup> The Senate passed the remainder of the bill on June 15, 2011.<sup>25</sup> As the 2011 session drew to a close, the Senate leadership postponed consideration of the drug immunity issue to the 2012 short session.

### CONCLUSION

If the immunity bill becomes law, North Carolina will join Michigan and Texas as the only “safe havens” in the United States for multinational companies to sell dangerous and defective drugs. That would be a disaster for North Carolina consumers, and violate the fundamental principle that every person and corporation should be accountable for their conduct. We look forward to working with legislators from both parties to defeat the drug immunity bill.

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<sup>21</sup> Attorney General Roy Cooper, “New Provision Could Leave North Carolina Taxpayers Out of National Refunds” (Press Release, April 14, 2011). North Carolina received a \$1.8 million dollar settlement from Merck to settle its Vioxx-related claims. [http://www.ncdoj.gov/News-and-Alerts/News-Releases-and-Advisories/Press-Releases/Drug-maker-to-pay-\\$58-million-to-NC-and-29-other-s.aspx](http://www.ncdoj.gov/News-and-Alerts/News-Releases-and-Advisories/Press-Releases/Drug-maker-to-pay-$58-million-to-NC-and-29-other-s.aspx). The Michigan immunity bill blocked Michigan’s Attorney General from pursuing similar claims against Merck.

<sup>22</sup> House Bill 542, Third Edition Engrossed 6/1/11 (Section 2.2).

<sup>23</sup> Statement from Attorney General Cooper on House Bill 542 (June 1, 2011).

<sup>24</sup> House Bill 542, Senate Judiciary Committee Substitute Adopted 6/13/11.

<sup>25</sup> House Bill 542, Fifth Edition Engrossed 6/15/11.



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